

REMARKS

This is in response the Office Action of May 9, 2007. Claims 1-35 are pending in the present application, wherein claims 9-35 were previously withdrawn in response to the restriction requirement of February 1, 2006. Applicants are filing a Request for Extension of Time in accordance with 1.136(a) with this response.

In the Office Action, the Examiner **1)** rejected claim 5 under 35 USC §112 as being indefinite; **2)** rejected claim 8 under 35 USC §101 because the claims improperly set forth a method; **3)** rejected claims 1, 4, 5/1, 5/4, 7/1, 7/4, 8/1 and 8/4 under 35 USC 103(a) as being unpatentable over US 5,649,903 to Deniega in view of US 5,591,337 to Lynn; **4)** rejected claims 2, 3, 5/2, 5/3, 7/2, 7/3, 8/2 and 8/3 under 35 USC 103(a) as being unpatentable over Deniega in view of Lynn and further in view of US 5,858,015 to Fini; **5)** rejected claims 6/1 and 6/4 under 35 USC 103(a) as being unpatentable over Deniega in view of Lynn and further in view of US 5,423,738 to Robinson; and **6)** rejected claims 6/2 and 6/3 under 35 USC 103(a) as being unpatentable over Deniega in view of Lynn and in view of US 5,858,015 to Fini and further in view of US 5,423,738 to Robinson.

In response to the Office Action, Applicants have amended independent claim 1 to further distinguish over the cited references. Applicants have also amended independent claim 1 to eliminate certain features that are not being relied upon to distinguish the prior art. Applicants respectfully submit that amended independent claim 1 and the respective dependent claims would not have been obvious over the Deniega patent, either alone or in combination with the Lynn patent.

Specifically, amended claim 1 of the present application, as previously set forth,

requires a blood processing system comprising a blood processing set including a source of blood cells and a blood component collection flow channel coupled to the source of blood cells. The blood component collection flow channel includes a blood cell storage container and an in-line filter to remove leukocytes from the blood cells before entering the blood cell storage container. The in-line filter includes a fibrous filter medium and first and second flexible housings. A pump station is adapted to be placed into communication with the blood component collection flow channel to pump blood into the blood cell storage container through the in-line filter. As amended, claim 1 now further requires a separate restraining structure contacting an outer surface of each of the first and second flexible housings to restrain the outward expansion of said housings under pressure applied during operation of the pump station. Support for the amendments to claim 1 can be found on at least page 12, paras. [0187-0191] of the application as filed.

Claims 1, 4, 5/1, 5/4, 7/1, 7/4, 8/1 and 8/4 Would Not Have Been Obvious Over US 5,649,903 to Deniega in view of US 5,591,337 to Lynn

Applicants submit that amended independent claim 1 and the respective dependent claims would not have been obvious over Deniega either alone or in combination with Lynn for several reasons, as described below.

First, Deniega does not describe blood processing set comprising, among other things, a separate restraining structure contacting an outer surface of each of a first and second flexible housings to restrain the outward expansion of the housings under pressure applied during operation of a pump station as required by amended claim 1.

By restraining expansion of the filter with a separate restraining structure that contacts an external surface of each housing, the pump cannot unduly expand the filter, and thus the total blood volume in the filter is kept to a low amount during the filtration process which potentially decreases filtration time and increases the red blood cell recovery percentage following leukofiltration. See page 12, para. [187]-[189].

As acknowledged in the Office Action, Deniega does not describe a leukocyte filter comprising two flexible housings with a fibrous filter medium. Deniega describes only a rotatable membrane separator apparatus (60b) for filtering leukocytes from a blood component. The rotatable membrane separator generally comprises a cylindrical rotor or spinner that is rotationally mounted within a housing, creating a space or gap for fluid flow between the membrane and the housing. However, there is nothing in Deniega to suggest that the rotatable membrane separator in Deniega includes a separate restraining structure contacting an outer surface of a first and second flexible housings, or how or where a restraining structure, as presently claimed, could be added. The Office Action, however, points out that Lynn does disclose a fibrous leukocyte filter with a flexible housing. The Office Action concluded that it would have been obvious to combine Deniega with Lynn to achieve the claimed subject matter.

However, even if one of ordinary skill were to combine the teachings of Deniega and Lynn, the claimed blood processing system comprising the above-described restraining structure would still not be achieved, and there is no logical extension of Deniega or Lynn to render obvious the subject matter of the amended claims obvious. Accordingly, for at least these reasons, amended independent claim 1 and the respective dependent claims would not have been obvious over the cited references.

Claims 2, 3, 5/2, 5/3, 7/2, 7/3, 8/2 and 8/3 Would Not Have Been Obvious Over Deniega
In View Of Lynn And Further In View Of US 5,858,015 To Fini

Applicants note that claims 2, 3, 5/2, 5/3, 7/2, 7/3, 8/2 and 8/3 are dependent from amended independent claim 1. Accordingly, and for the reasons already stated hereinabove, claim 1 would not have been obvious in view of Deniega and Lynn, and therefore, claims 2, 3, 5/2, 5/3, 7/2, 7/3, 8/2 and 8/3 (which are dependent on claim 1) also would not have been obvious over Deniega either alone or in combination with Lynn.

Further, the Fini patent does not disclose or render obvious any of the subject matter missing from the Deniega patent and the Lynn patent and is not properly combinable with Deniega and/or Lynn to render the claimed subject matter obvious. As noted above, neither Deniega nor Lynn teaches the separate restraining structure as required by amended claim 1. Further, and as acknowledged by the Examiner in the Office Action, Deniega does not teach of using fibrous filter medium comprised of two flexible housings as required by claim 1. It is respectfully submitted that even if one were to combine the Deniega blood processing system with the filter of Lynn, and further combine the teaching of Deniega and Lynn with the rigid support of Fini, the resulting device would still not have the features of the claimed blood processing system.

For example, Applicants note that Fini simply describes a container/reservoir for collecting blood. The container of Fini generally comprises two parts: a flexible membrane (expandable) portion (7) welded to a more rigid portion (6). Together, the

expandable membrane portion and the rigid portion form a closed, expandable space or container. However, that is not the claimed invention here. Amended claim 1 specifically requires a separate restraining structure contacting an outer surface of each of a first and second flexible housings to restrain the outward expansion of the housings under pressure applied during operation of a pump station, whereas the subject matter in Fini can only be fairly read as a container comprised of two portions, with only one portion being more rigid than the other portion. The container of Fini clearly does not include a structure that can be construed or understood to be the separate restraining structure as presently claimed.

Applicants further note that a basic question underlying the Examiner's rejection is why would it have been obvious to a person skilled in the field to take the rigid portion of the blood collection container of Fini and combine it with Deniega and Lynn to achieve the claimed subject matter. It is respectfully submitted that there is no logical design reason to do so, except one based on the improper use of hindsight to try to put together disparate references for the sake of trying to render the claimed invention obvious. The Supreme Court in KSR fully recognized that it is improper to use hindsight in the evaluation of obviousness, and the Supreme Court made no change in the law in that respect.

It is therefore respectfully submitted that it would not have been obvious to combine the blood processing system of Deniega with the filter of Lynn and the rigid container portion of Fini to achieve the claimed subject matter. And further, even if such a combination were made, it would not result in a blood processing system so as to remove leukocytes from blood cells by passing a blood component through a fibrous

filter medium wherein a separate restraining structure contacts an outer surface of each of a first and second flexible housings to restrain the outward expansion of the housings under pressure applied during operation of a pump station required by amended claim 1. There is no description of such in Fini nor is there any basis for concluding that such a structure on the claimed combination would have been obvious.

Claims 6/1, 6/2, 6/3 and 6/4 Would Not Have Been Obvious over Deniega in view of Lynn and Further In View of US 5,423,738 to Robinson And/Or US 5,858,015 to Fini

Applicants note that claims 6/1, 6/2, 6/3 and 6/4 are also dependent on amended independent claim 1. The added Robinson patent does not disclose any of the subject matter missing from the Deniega, Lynn or Fini patents and is not combinable with Deniega and/or Lynn to render the claimed subject matter obvious. Accordingly, and for the reasons already stated hereinabove, claim 1 would not have been obvious in view of Deniega either alone or in combination with Lynn, and therefore, claims 6/1, 6/2, 6/3 and 6/4 (which are dependent on claim 1) are also would not have been obvious by the cited references.

Conclusion Regarding Non-Obviousness

For the reasons above, it is respectfully submitted that amended claim 1 and the respective dependent claims would not have been obvious over the cited references.

Claim 5

Applicants have amended claim 5 to include antecedent basis for the claimed controller. Withdrawal of the objection to claim 5 is respectfully requested.

Claim 8

Applicants have amended claim 8 to better recite the claimed method by including the recitation of the active, positive steps included in the method. Support for the amendment to claim 8 can be found in the specification of the present application at least at pg. 1, paras. [0008]-[0011]. Withdrawal of the rejection of claim 8 is respectfully requested.

General Conclusion

For the reasons set forth above, Applicants respectfully submit that the pending claims are allowable. Accordingly, the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

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